Pfizer Canada Inc.
P.O. Box 800 / C.P. 800
Pointe-Claire/Dorval, (Québec) H9R 4V2
Tel/Tél. (514) 695-0500 Fax/Téléc. (514) 426-6835

Pfizer Canada Inc.

October 6, 2008

Sylvie Dupont
Secretary of the Board
Patented Medicines Prices Review Board, (PMPRB)
P.O. Box L40, Standard Life Centre
333 Laurier Avenue West, 14th floor
Ottawa, Ontario
K1P 1C1

Dear Ms. Dupont;

As per the Board's August 2008 invitation for feedback on its *Draft Revised Excessive Price Guidelines* package, Pfizer Canada has had an opportunity to review the material in some detail. The attached document outlines Pfizer's specific views on those areas where it has questions, comments and concerns.

First, I must state for the record, Pfizer's fundamental opposition to government intervention in the pharmaceutical markets via price regulation. As we have indicated before, Pfizer believes that a healthy competitive marketplace is the most appropriate way to ensure that prices for a given good reflects the best value for purchasers. Price controls impede the proper functioning of the market and create artificial incentives which distort the true value of the products being sold. Canada's experience with the PMPRB during these past twenty years has only solidified that view.

Yet, Pfizer recognizes that the establishment of the Board was a vital public policy trade-off which paved the way for the Canadian government to resurrect important intellectual property protection rights for pharmaceuticals that had been denied for twenty years previously. Its role, as acknowledged by the Board in the notice and comment package, is to safeguard the Canadian public from "excessive" pharmaceutical prices resulting from the market exclusivity garnered through enhanced patent protection.

According the Board's own standards, the pricing performance of the Canadian patented pharmaceutical industry since its establishment has been compliant. The majority of new patented medicines are introduced at prices which are well below the maximum non-excessive price (MNE) established by the Board and year-after-year, the average price increase has been less than the consumer price index (CPI).

Pfizer participated collaboratively in the various consultations conducted. The consultations resulted in a multi-stakeholder consensus which was an integrated package which should not be tampered with in order to avoid undermining the compromises that had been reached. Yet, the package presented by the Board has omitted some vital elements which serve to make the entire proposal unacceptable to Pfizer.

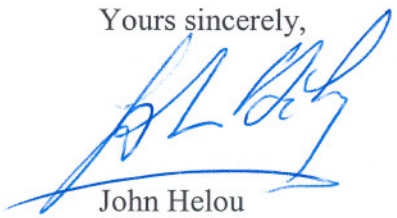
The key flaw in the proposed revisions is the Board's unwillingness to actually de-link the average transaction price (ATP) of a given medicine from its MNE. As a result, the system forces prices down over time because of benefits offered by the manufacturer. The Board has failed to achieve its stated objective – to avoid creating disincentives for offering financial benefits to customers. The benefits the Board is jeopardizing are patient assistance programs to provide access while provincial formularies are deciding to cover medicines. The Board is also discouraging discounts to provincial formularies which could mean higher drug prices. These disincentives brought about by PMPRB could lead to unnecessary federal provincial / federal tensions in health. These changes also serve to weaken Canada's reputation as a jurisdiction in which to invest which is contrary to the government's objectives

Given the Board is contradicting its own goals and those of the government; Pfizer strongly encourages the Board to reconsider the entire package and to re-work it in a manner which reflects the consensus achieved among stakeholders. Doing so would nullify a long list of potential critics. Re-working it as per our comments will lead to a workable solution which will eliminate the disincentives manufacturers face when offering free medicine and savings to customers.

Finally, Pfizer wishes to endorse the submission from Canada's Research-based Pharmaceutical Companies (Rx&D). The Rx&D feedback is an integral component of our input.

Thank you for your consideration of these views.

Yours sincerely,



John Helou
Vice-President
Public Affairs & Stakeholder Relations

c.c. The Hon. Tony Clement, Minister of Health
The Hon. Jim Prentice, Minister of Industry

Pfizer Canada's
Response to the PMPRB's
Draft Revised Excessive Price Guidelines
October 2008

Introduction

In response to the request for comments addressing the Patented Medicine Prices Review Board's (PMPRB's) *Draft Revised Excessive Price Guidelines* please see Pfizer Canada's commentary below.

Pfizer's submission should be considered as a supportive addition to the input provided by Canada's Research-Based Pharmaceutical Companies, (Rx&D). Pfizer endorses the views expressed by Rx&D, but simply wishes to expand on those comments from the perspective of a patentee which will be required operationally to adhere to the new guidelines.

Commentary on the Consultation Process

Before addressing the eight issues addressed by the Board, Pfizer would like to make a few comments about the consultation process itself.

Pfizer wishes to remind the Board that this consultation started in 2005 as an attempt to address a perceived threat of the deterioration in the traditional pricing stability within the patented pharmaceutical marketplace in Canada (a threat which the Board later acknowledged as exaggerated). From Pfizer's perspective, the burgeoning scope of the proposed reforms and their potential impact on the marketplace are far greater than the issues that prompted the consultation in the first place.

By most objective standards, there is no particularly compelling reason to seek substantive changes to the way the Board operates. While stakeholders have identified a number of minor irritations and complaints over time, no pressing public policy need for wholesale changes has emerged. Yet despite the relative stability of the pricing environment for the past twenty years and the absence of compelling calls for reform, the Board has persisted in driving forward with its reform agenda. And in response, affected stakeholders have been obligated to participate in a drawn-out process of unrelenting consultations. If the reporting and guidelines are implemented as outlined, it will make a tolerable situation much worse than when the process started.

The Need to Respect the Multi-stakeholder Consensus Achieved

In the end, the most distressing aspect of this process has been the Board's inability to endorse fully the consensus achieved among a group of diverse stakeholders who, generally speaking, would not have been expected to see eye-to-eye. Throughout the process, working group participants demonstrated a great deal of compromise and

flexibility in order to find practical solutions which would meet the public interest without undermining the legitimate aspirations of any of the key players.

The fact that consensus was reached at all within the various working groups on a number of very controversial topics should be viewed as a remarkable achievement. Yet, by "cherry-picking" and/or altering the working group recommendations, the Board has undermined that important work. Therefore, the Board should not be surprised to learn that those stakeholders who worked so hard to find common ground might not view the resulting draft guidelines as acceptable.

As an active participant in the various working group exercises, Pfizer can attest to the good will and the thoughtful consideration on the part of all collaborating stakeholders. This spirit of pragmatism led to the various compromises which formed the backbone of the working group recommendations.

As was pointed out to Board staff, the multi-stakeholder consensus achieved by the various working groups contained a number of delicate concessions in return for other considerations. These compromises were vital to holding the proposals together as a cogent, integrated package and creating something that would be acceptable to all parties. The absence in the draft guidelines of numerous key elements of that package represents a critical undermining of the whole agreement and renders many of the retained proposals flawed as a result of important trade-offs being left aside by the Board.

For example, while the notion of the "dip" proposed by the Working Group on Price Tests has been endorsed by the Board and integrated into the draft guidelines, its companion, the "gap" concept has not. The Board's choice of one over the other demonstrates a fundamental misunderstanding of the de-linking concept. Without both the "dip" and "gap" elements, the proposal is incomplete and therefore, invalid.

The accord reached by the Working Group on Therapeutic Improvement also was altered after-the-fact by the Board. In this case, the Board rejected some of the proposed criteria to be utilized by the Human Drug Advisory Panel (HDAP) in assessing levels of therapeutic improvement, even though the working group had agreed that they should be accounted for.

The inclusion of generic versions as part of the Board's calculations related to the International Therapeutic Class Comparison (ITCC) Test is another example of the Board undermining the compromises reached. In this case, the ITCC Working Group expressly recommended that generic medicines be excluded in an ITCC unless the MNE would be determined as being no higher than the top of the applicable ITCC. Given the diverse membership of the working group, the Board should assume that this recommendation was made for fair and good reasons and negotiated in good faith by those involved. Therefore, there is no reason to second-guess that agreement.

As such, Pfizer urges the Board to reconsider the working group recommendations as a coordinated package, keeping in mind that, success depends on viewing them in an

integrated fashion. Pfizer encourages the Board to re-work the draft guidelines accordingly to ensure that all the key elements of the consensus achieved at the working group level are respected.

Addressing the Issues Identified by the Board

Underlying Principles

Pfizer disagrees with the inclusion of language in the guidelines related to the Board's "consumer protection" mandate, as that would be a misrepresentation of the Board's purpose to determine "if a medicine is being sold or has been sold at an excessive price". The addition of language in the guidelines related to protecting consumers would only exacerbate an already unbalanced situation.

Levels of Therapeutic Improvement

The efforts of the Working Group on Therapeutic Improvement provides an excellent example of the capacity of a group of stakeholders with differing perspectives to achieve an understanding with which all parties can live. Pfizer was able to endorse the working group report on the basis of the accord reached, even though it disagrees with the premise on which it is based. Therefore, it is disappointed by the Board's decision to restrict the criteria developed by the working group which will be used by the HDAP to assess levels of therapeutic improvement.

In reality, the research-based pharmaceutical industry believes that there is no particularly valid reason for the Board to try to make distinctions regarding the level of therapeutic improvement related to a given medicine in comparison to others. However, in the spirit of compromise, it was willing to accept instead, the addition of a fourth category recognizing moderate improvements. Of course, concerns remain about how the selection process will be administered and the amount of time and resources required to make such determinations. It is admirable that a workable solution was reached by the working group and therefore, like the industry, the Board should respect that agreement.

International Therapeutic Class Comparison Test

Pfizer endorses the Rx&D position on this matter and has nothing further to add.

Introductory Price Tests

As indicated in the Rx&D submission, Pfizer would prefer to see the process of determining whether an introductory price of a new patented medicine is excessive streamlined considerably. We also share the association's concerns about certain changes to the guidelines related to the Reasonable Relationship (RR) and Therapeutic Class Comparison (TCC) Price Tests.

In reviewing the revised Schedule 5 addressing the calculation of RR, it appears that a substantial change has been made to the "Different Strength Test". Under the current guidelines, the price of a lower dose of a given medicine is permitted to be equal to the price of the highest dose. This is a necessary measure to insure that no disincentive is created for the launch of, amongst others, titration dosages. It is also a reflection of the pharmaceutical marketplace in which prices are not necessarily linear to the quantity of active ingredient. However, according to the draft guidelines, the ATP of the new lower dose would be restricted to a ratio equivalent to the difference in strength of the dose. This change is simply unacceptable.

Similarly, we note the omission in the revised guidelines of an important alternative to the TCC when that test is not appropriate, where priority should be given to international prices.

It is unclear if these changes have been made intentionally since there has been no consultation by the Board regarding the possibility of changing either provision. Section 96 (5) of the patent act is very specific: "*Before the Board issues any guidelines, it shall consult with […] representatives of the pharmaceutical industry*". Neither Pfizer nor Rx&D were consulted.

Modified Guidelines for Certain Patented Generic Drug Products

Pfizer has no comments on this matter.

De-Linking the ATP from the MNE Price

The Working Group on Price Tests developed a creative means to grant manufacturers the required pricing flexibility that would not jeopardize their capacity to offer legitimate benefits to people in need. The rationale for the approach is twofold:

First, it respects the fact that, if the price of a medicine is determined to be non-excessive at a given point in time, then it must be unreasonable, at a later date, to find the same medicine to be excessive when it is priced lower than the earlier, previously non-excessive price. Second, it is intended to permit manufacturers to respond to market forces without the prospect of the penalty of forcing the price of the medicine down due to some arbitrary averaging calculation.

Unfortunately, the Board's rejection of the working group's "Gap" concept means effectively that the ATP has not been de-linked from the MNE. Moreover, the Board's rationale for rejecting this concept is not explained adequately. To be precise, the Board must appreciate that the combination of the "Dip" and "Gap" concepts operating together was the key to being able to meet the Board's requirement for reporting of all financial benefits without undermining the capacity of patentees to offer incentives or provide medicines to address compassionate needs. Permitting one without the other nullifies the value of the arrangement.

The result is price regulation scheme which creates an obvious disincentive for companies to offer any benefits in order to avoid reducing the allowable price of medicines over time. This outcome is in direct opposition to the Board's stated wish not to "unduly create a disincentive to the offering of benefits to customers." In fact, the absence of a "Gap" more likely will ensure that companies will feel compelled to maximize the price charged in the marketplace and completely discourage the contemplation of any financial considerations in future.

Pfizer notes that, in the discussion paper, the Board is said to have a concern about the potential price increases that could result beginning in January 2009 from the proposed "**C**ap" methodology. According to the document, that concern arises in the light of the mandatory reporting of all benefits as part of an ATP calculation. However, in reviewing the draft, it appears that an error was made. We assume that the concern identified is actually related to the proposed "**G**ap" methodology. If that is the case, then the Board must understand that any allowable price increases permitted as part of addressing a "gap" would not have anything to do with any benefits offered.

In Pfizer's view, acceptance of the "gap" and "dip" methodologies represents the ideal situation. It would permit the PMPRB to continue to meet its public policy objective of ensuring that patented pharmaceutical prices are not "excessive", but would otherwise get the Board out of the way of the marketplace forces which, in reality, are a much more effective means of controlling price increases.

<u>"Any Market" Price Reviews</u>

As an initial comment in this regard, Pfizer wishes to express its continuing opposition to the concept of "any market" price reviews by the PMPRB. While it is recognized that the *Patent Act* makes reference to "any market", the company feels that government price controls which would have the effect of artificially eliminating pricing variability amongst different customers, even in cases where none of the differential prices are higher than the national MNE, would be an unwarranted intrusion into the marketplace. This practice would create yet another significant barrier to any patentee which otherwise might consider offering financial incentives to customers. Pfizer continues to hold this view, even in recognition of the Board's concession that "any market" reviews should only be conducted at the time of product introduction. "Any market" review cannot exist without a redefinition of the MNE and the implementation of the GAP methodology, where the MNE never decreases and where it is determined based on the highest "market specific ATP". This view is consistent with the recommendation of the Working Group on Price Tests.

More importantly, in attempting to impose its jurisdiction over internal domestic market segments, the Board will create a requirement for much more complex monitoring infrastructure, more bureaucratic hoops for patentees to jump through and the prospect of considerably more disputes with patentees – all without any compelling evidence that a problem exists which demands attention.

Yet, even if an argument could be made that it is in the public interest to address pricing differentials between different classes of customer, there is a real challenge in determining exactly what constitutes a defined market. Consider that fact that the PMPRB currently divides the marketplace arbitrarily by four customer classes – wholesalers, pharmacies, hospitals and other. Given that Pfizer supplies all its medicines to hospitals and pharmacies through wholesalers, in which market segment would the Board consider Pfizer products to be and how could they justifiably be comparing the prices of Pfizer medicines to those of competing companies which may distribute their medicines directly? And how can the Board argue that wholesalers and pharmacies are two different markets when in fact they are simply two ways of distributing in the same market? These and numerous other key questions have not been addressed in the Board's effort to impose a new regulatory burden on patentees.

Clearly, more consultation is called for in order to define "markets" in a reasonable manner. And it must be questioned whether the time, effort and implications of such a practice are even justified. Pfizer argues that they are not.

Re-setting the MNE Price

Pfizer has no additional comments to offer to those expressed in the Rx&D submission in this regard.

Responding to Board Requests for Input

Calculating Excess Revenues Related to "Any Market" Investigations

When considering "any market" reviews, it is important to ensure that the calculation of excess revenues related to a finding of "excessive" pricing is done as fairly as possible. When considering this question, the Board must recognize that the ATP, on which a determination of excess would be based, is, by definition, an average. This means that some prices in the marketplace must be higher and some lower. If, in calculating excess revenues against only those generated in the market where the price is determined to be "excessive", it would not take into account the markets where the price is lower than the ATP. That would be inherently unfair. Therefore, excess revenues should be based on the national ATP and not just the excess revenue for the market where the price is determined to be "excessive".

Views on the CPI Cap

In response to the Board's request for comments regarding its practice of capping the amount of single year price increases at 1.5 times the CPI, Pfizer would suggest that it be eliminated.

As it is, the combination of other PMPRB provisions and a host of pricing regulations at the provincial level makes the prospect of actually taking a price increase a daunting and complex prospect for any patentee. As a matter of operational reality, there is little

opportunity in Canada for manufacturers to take annual price increases. One need only look at the record since long-standing price freezes have been lifted in Ontario and Quebec. PMPRB reports of average annual price increases since that time (consistently well below the inflation rate) have demonstrated conclusively that, despite the capacity to take inflationary price increases, the market has been effective in reducing manufacturers willingness to do so. Therefore, the CPI cap is largely redundant and, in keeping with widespread political commitments to reduce regulatory burden, should be discontinued.

It might be remembered that the CPI cap was introduced in 1994 as a means of helping payers avoid facing the prospect of significant budgetary pressure due to price increases introduced in compliance with PMPRB rules which might arise in times of high inflation. It is useful to note at this point that the proposed "gap" methodology rejected by the Board would have a similar moderating effect on one-time price increases and, if implemented, could offer payers a measure of budgetary planning comfort. The one year cap rule (1.5 x CPI x Previous ATP) links the MNE to the ATP thus providing a major disincentive to provide benefits that would lower the ATP. This could create a situation where prices to some customers are above the MNE yet not excessive. This clearly is a paradoxical and unacceptable situation.

Concluding Remarks

Pfizer has developed these comments in good faith and in anticipation that they will be given full consideration by the Board. However, it must be noted that the experience of the past several years does not provide any measure of comfort that the time and effort expended in contributing to the current consultation will have any more effect than it has previously.

As was stated in Pfizer's August 2006 response to the Board's May 2006 discussion guide,

> *"Given the lack of significant stakeholder concern about the threat of potential price increases and the fact that recent increases have been in full compliance with PMPRB regulations … there appears to be little public policy rationale for a process that could lead to further price regulation … After almost twenty years of experience, it is clear that innovative pharmaceutical companies have refrained from abusing their patent rights through the charging of excessive prices … Given the responsible pricing of patented medicines during a long period of time, the Board should use this opportunity to consult stakeholders publicly regarding how it can* ***reduce*** *(emphasis added) its regulatory burden and streamline current processes for patent holders and other stakeholders."*

In Pfizer's view, nothing has changed since then. Yet, the Board persists in pursuing an agenda which will have the opposite effect – a widening of the regulatory net, more detailed and complex reporting requirements and the imposition of new requirements which will eliminate what little potential there is for customers to negotiate favourable terms with manufacturers. In our estimation that represents a net loss prospect for

Canadians. Therefore, Pfizer encourages the Board to engage in a fundamental review of the objectives of these current reforms. At very least, Pfizer urges the Board to appreciate and honor the significant effort that was made by a range of very diverse stakeholders in the development of the various working group recommendations. As such, the Board should re-work its current proposals to accept all those recommendations as a comprehensive package and re-issue them before proceeding with any changes.

Thank you for the opportunity to comment. We look forward to further dialogue aimed at addressing the concerns raised.